

REMARKS

Claim 1 has been amended to clarify that the block copolymer is completely amorphous at human body conditions. Support for this amendment is found on page 9 at lines 23-30. A corresponding amendment has been made to claim 2.

Claims 32-35 have been canceled as directed to a non-elected invention. However, the process claims, claims 25-31 and 36 and 39 remain as rejoinder may be possible.

All of the rejections are made over the art.

The Rejection for Anticipation

Claims 1-3, 6-9, 12, 16, 17 and 19-23 were rejected as assertedly anticipated by Langer (U.S. 6,160,084).

This rejection rests on the premise that the polymers in Table 5 of Langer show examples of compositions that are amorphous at human body temperature. In part, this rested on the assumption that the claimed compositions need not be completely amorphous, and the claims have been amended to include that limitation.

Thus, with that limitation in mind, Table 5 needs to be evaluated in terms of whether the disclosed polymers are or are not completely amorphous.

As shown in Table 5, PDL30, PDC27, PDC31 and PDC40 all have hard segments with melting points well above human body temperature. These hard segments will contain regions of crystallinity and therefore these polymers, at least, fail to anticipate the claimed compositions. However, PDL23 and PDC22 do not have a temperature listed for the hard segment which, as Table 3 shows, is PDS.

An explanation of the data in Figure 5 is provided in the enclosed Declaration by one of the inventors, Dr. Flipsen. For PDC22, the melting temperature of the soft segment is given as 35.0°C. Since the hard segment is required by the specification to have a melting point at least 10°C higher,

the missing number for the melting temperature of the hard segment must be at least 45°C. For PDL23, a T_g of 34.5 is provided and this represents the T_g for the soft segment, so the T_m for the hard segment must be at least 44.5°C. Both of these are above human body temperature, and thus, these compositions contain hard segments with some crystallinity. Since both polymers contain portions of crystallinity, they do not meet the now-present claim limitation of completely amorphous character.*

Since claim 1 is not anticipated, neither are claims 2-3, 6-9, 12, 16, 17 and 19-23 dependent thereon which were included in this basis for rejection.

Claims 4-5, 10-11, 13-14 and 18 were rejected as obvious over Langer. It is noted that sheet 2 (Lactide pricing information, Alfa Aesar) is provided as extrinsic evidence.

This rejection depends completely on the finding of anticipation of claim 1 by Langer. Since that rejection has been overcome, so, too, is the rejection of the dependent claims for obviousness.

Claims 4 and 13-15 were rejected as obvious over Langer in view of Rashkov, *et al.*, (*Macromolecules* (1996) pp. 50-56). Again, the secondary reference is cited for disclosures of additional limitations set forth in these claims. As above, this basis for rejection depends on the conclusion that claim 1 is anticipated by Langer, which is no longer the case. Therefore, this rejection, too, may be withdrawn.

For completeness, the following comments apply to the Response to Arguments set forth beginning on page 10 of the Office action. As to paragraphs 32-35, these responses depend on the previous failure of claim 1 to require completely amorphous character. Thus, they are no longer applicable.

* The Fox equation is irrelevant in this context as it is employed to calculate T_g of mixtures. The critical issue here is T_m of the hard segment which mandates crystallinity.

As to paragraph 36, the failure of Table 5 of Langer to set forth a second T_m has been explained in the enclosed Declaration of Dr. Flipsen. The omission of the second temperature is simply an omission, not an indication that the listed T_m or T_g describes the entire composition. As to paragraphs 37-42, it is believed that these comments are no longer apposite in view of the amendment to the claims and the explanation in Dr. Flipsen's Declaration.

As to paragraphs 43-46, the requirement in the claims that the compositions be completely amorphous under human body conditions is responsive. In particular, with respect to the measurement by Langer of T_{trans} in a dry state, this is irrelevant as the absorption of water will only occur if the copolymers are soluble. The copolymers in Table 5 of Langer all have PDS as the hard segment, and PDS is water-insoluble. Thus, it does not matter whether Langer's measurements were under dry or wet conditions; for an insoluble polymer, the results will not change.

As to paragraph 47, obtaining the composition with the now-required properties with the described components is simply a matter of varying quantities and level of crosslinking – all within the ordinary skill of the art.

As to paragraphs 48-49, applicants' position is not that it would be impossible for Langer's materials for general use to have a low transition temperature of the hard segment, but rather to the extent they have memory when used within the human body, it cannot be the case that these low temperatures are possible. The crystallinity must be retained in order to achieve the memory property.

As to paragraphs 50-51, applicants apologize for omitting to attach the Lendlein and Langer article to the previous response. As noted in the previous response, this document does show at least semi-crystallinity. The requirement for solubility of the polymers in order for there to be a difference between crystallinity in the wet and dry state has been noted above, and thus, the measurements of Lendlein and Langer in the dry state will not affect the results.

As to paragraphs 52-55, the rejections for obviousness by combining Langer with additional documents have been addressed by noting that these rejections depend on anticipation of claim 1 by Langer. Since Langer does not anticipate claim 1, any such modifications are irrelevant. Langer's polymers do not remain completely amorphous under human body conditions and thus cannot "retain" these properties using the modifications set forth in claims 4, 5, 10, 11, 13, 14 and 18.

Conclusion

In view of the amendment to the claims and the evidence presented by Dr. Flipsen, applicants respectfully submit that claims 1-23 are patentable over the cited art. As these claims are allowable, the process claims, claims 25-31 and 36 and 39, may be rejoined and allowed as well. Passage of these claims to issuance is respectfully requested.

Should minor issues remain that could be resolved over the phone, a telephone call to the undersigned is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 313632002300.

Dated: April 12, 2011

Respectfully submitted,

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